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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/518,752

07/01/2005

Katayoon Dehesh

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EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT

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1638

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/518,752	<b>Applicant(s)</b> DEHESH ET AL.	
	<b>Examiner</b> Elizabeth F. McElwain	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11, 14-27 and 30-33 is/are pending in the application.
- 4a) Of the above claim(s) 4, 5 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-11, 14-27 and 31-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

The amendment filed April 29, 2008 has been entered.

Claims 1, 14 and 24 are currently amended.

Claims 31-33 are newly submitted.

Claims 12, 13, 28 and 29 are cancelled.

Claims 1-11, 14-27 and 30-33 are pending.

Claims 1-3, 6-11, 14-27 and 31-33 are drawn to the elected invention and are examined on the merits.

### ***Election/Restrictions***

1. This application contains claims 4, 5 and 30 are drawn to an invention nonelected with traverse in the reply filed on November 5, 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Claim Objections***

2. Claims 10 and 11 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. There is no antecedent basis for fragments in claim 1 on which they depend.

3. Claim 31 is objected to for depending on claim 31, as there is no antecedent basis in claim 31 for a soybean plant. Claim 31 has been examined as if it were dependent on claim 32. However, this does not relieve applicants of the requirement to correct the claim dependency.

***Claim Rejections - 35 USC § 112***

4. The rejection of claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in view of applicants' arguments.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 14-27, 32 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn to soybean plants and seeds transformed with the FATB thioesterase intron I of SEQ ID NO: 2 or a sequence 90% identical to SEQ ID NO: 2, and wherein the soybean plant or seed has reduced levels of palmitic or stearic acid relative to a nontransformed plant. Claims are also drawn to plants and seeds produced by transforming a soybean plant with said sequence; and a second set of DNA sequences encoding one or more of a beta-ketacyl-ACP synthase I, a beta-ketacyl-ACP synthase IV and a delta-9 desaturase. And new claims 32 and 33 are broadly drawn

to soybean plants that are capable of expressing a nucleic acid comprising any FATB intron, complement thereof or fragments of at least 25 contiguous nucleotides of either, and a second nucleic acid encoding one of the enzymes set forth in the claims, and wherein the plant exhibits an oil composition with 15% or less saturated fatty acid content. However, the specification does not disclose any soybean seeds transformed with said constructs and the specification does not disclose any soybean plants having reduced levels of either palmitic or stearic acid relative to a nontransformed plant, as stated in the last office action and as modified due to claim amendments.

7. Applicants' arguments filed April 29, 2008 have been fully considered but they are not persuasive. Applicants' argue that examples of transformed soybeans are provided in Examples 2 and 3 and Table 1. However, the data provided in Table 1 relates to soybean plants transformed with constructs comprising the FATB II intron of SEQ ID NO: 3, **not** comprising SEQ ID NO: 2. In addition, the construct transformed into the soybean plants of Table 1 did not comprise any of the second nucleic acid coding sequences as set forth in claims 7-9, 24-27, 32 and 33. Applicants are pointing to data that does not relate to what is claimed.

8. Applicants further argue that the specification teaches how to prepare other constructs having sequences from FATB genes, as well as with additional genes and that one of skill in the art would be able to make and use said constructs to selectively reduce the level of an endogenous FATB protein or transcript. In addition, applicants assert that the expression of additional genes set forth in the claims would also be recognized to decrease the percentage of saturated fatty acids. Applicants further argue that the references cited by the Examiner do not support an argument for unpredictability, stating that De Luca merely describes general

unpredictability; Voelker teaches the unpredictability of transformation with heterologous sequences, while the present invention relates to soybean plants transformed with nucleic acids from soybean; and Topfer et al relates to expression of FATB coding sequences, not to FATB introns for the suppression of endogenous soybean FATB. Applicants restate that a working example has been provided in Examples 2 and 3, and Table 1. Finally, Applicants argue that the specification provides sufficient guidance for one skilled in the art to choose sequences and select for transformed plants, using routine steps.

9. The Examiner maintains that no examples are disclosed in the specification, which support enablement for the claimed invention, as stated above. The Examiner maintains that applicants assertions are speculative regarding the effect on a soybean plant that has been transformed with any of the vast multitude of possible constructs comprising SEQ ID NO: 2 or sequences that are as little as 90% identical thereto, and optionally co-transformed with an additional sequence coding for a fatty acid biosynthetic enzyme. The Examiner maintains that the cited reference establish the high level of unpredictability with regard to the levels of specific fatty acids that will be present in a plant transformed with nucleic sequences from genes for fatty acid modifying enzymes. Applicants have not disclosed the characteristics of any soybean plants that have been transformed with a construct comprising SEQ ID NO: 2 or similar sequences, much less any soybean plants that have been transformed with said construct in combination with an additional fatty acid modifying gene sequence, as recited in some of the claims. There is no guidance with regard to choice of sequence combinations, and no working examples of soybean plants having modified fatty acid profiles relative to non-transformed plants.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 7, 8, 10, 11 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dehesh et al (Plant J 15(3): 383-390, 1998) taken with Shoemaker et al (Database Accession AW568268, 3 Dec 2001), as set forth in the last office action and as modified due to the amendment of the claims.

12. The claims are drawn to recombinant nucleic acids comprising a sequence 90% identical to SEQ ID NO: 2 and operably linked to a promoter that functions in a plant cell for expression in the seed. Claims are also drawn to a recombinant nucleic acid comprising at least 25 nucleotides of the FATB thioesterase of SEQ ID NO: 2 or a sequence 90% identical to SEQ ID NO: 2; and a second set of DNA sequences encoding one or more of a beta-ketacyl-ACP

synthase I, a beta-ketacyl-ACP synthase IV and a delta-9 desaturase. New claim 31 is drawn to a nucleic acid sequence that has 100% identity to SEQ ID NO:2 over the length of said sequence or a complement thereof. Given the recitation of “a complement thereof”, the claim is interpreted to read on partial sequences that would have complementary regions to SEQ ID NO: 2.

13. Dehesh et al teach a recombinant nucleic acid comprising a napin seed-specific promoter operably linked to a FATB thioesterase gene sequence and said construct further comprising a coding sequence for a KAS IV gene (see page 389, the first column).

14. Dehesh et al do not specifically teach SEQ ID NO: 2.

15. Shoemaker et al teach a nucleotide sequence that is identical to the last 64 nucleotides of the 104 nucleotides of SEQ ID NO: 2. The sequence taught by Shoemaker et al is identified as an acyl-ACP thioesterase.

16. Given the recognition of those of ordinary skill in the art of having the construct of Dehesh et al comprising a plant seed-specific promoter operably linked to a plant FATB sequence and optionally to a second fatty acid biosynthesis genes, such as KAS IV for modulating fatty acid levels when transformed into a plant, it would have been obvious to modify this construct by substituting other known thioesterase sequences, such as the portion of SEQ ID NO: 2, as taught by Shoemaker et al. Thus the claimed invention would have been prima facie obvious as a whole at the time it was made, especially in the absence of evidence to the contrary.



17. Claims 3, 6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dehesh et al and Shoemaker et al as applied to claims 1, 2, 7, 8, 10 and 11 above, and further in view of applicants' admitted state of the prior art, as stated in the last office action, and as modified due to the claim amendments.

18. Dehesh et al taken with Shoemaker et al teach a recombinant construct comprising a plant seed-specific promoter operably linked to a plant FATB sequence of SEQ ID NO: 2 and optionally to a second fatty acid biosynthesis genes, such as KAS IV for modulating fatty acid levels when transformed into a plant.

19. Dehesh et al taken with Shoemaker et al do not specifically teach using a 7S promoter, that the nucleic acid is capable of expressing dsRNA or the construct additionally comprising a delta-9 desaturase coding sequence.

20. Applicants' admitted state of the prior art teaches that delta-9 desaturase genes were known (see page 9), and 7S seed specific promoters were known (page 24) and the use of double stranded RNA was known for disruption of gene expression (page 29).

21. Given the recognition of those of ordinary skill in the art of having the construct of Dehesh et al taken with Shoemaker et al for modulating fatty acid levels in a plant, it would have been obvious to modify this construct by substituting other known sequences as provided by applicants' admitted state of the prior art, such as the 7S promoter, or other known fatty acid biosynthesis genes, such as the delta-9 desaturase gene for the modulation of fatty acid levels. In addition, the use of a sequence that is capable of producing dsRNA would be optimization of process parameters and was taught in the prior art, as set forth by applicants in the specification.

Thus the claimed invention would have been prima facie obvious as a whole at the time it was made, especially in the absence of evidence to the contrary.

22. Applicants' arguments filed April 29, 2008 have been fully considered but they are not persuasive. Applicants argue that the sequence taught by Shoemaker is 40 nucleotides shorter than SEQ ID NO: 2, and that no motivation to combine the teachings of Dehesh and Shoemaker has been set forth. Applicants assert that there would have been no motivation to substitute a thioesterase coding sequence with a partial thioesterase sequence, and the claims have now been amended to read on the full length SEQ ID NO:2, and not fragments thereof.

23. The Examiner maintains that Dehesh teaches producing plants with modified levels of fatty acids by altering expression of both a thioesterase gene and a KAS IV gene. Applicants are claiming nucleic acid constructs for modifying thioesterase gene expression and optionally modifying expression of a second fatty acid biosynthetic gene, such as a beta-ketoacyl-ACP synthase. It is well known in the prior art that partial gene sequences are effective to modify expression of genes in plants, as evidenced in the specification (see page 29, the first full paragraph, for example). Therefore, one of ordinary skill in the art would have been motivated to substitute a partial thioesterase sequence that was known and taught by Shoemaker to produce a construct for modifying fatty acid levels in a plant, and the nucleic acid construct may further comprise a beta-ketoacyl-ACP synthase coding sequence to modify levels of both enzymes, as taught by Dehesh. One of ordinary skill in the art would have expected the claimed nucleic acid construct to modify fatty acid levels in a plant transformed with said construct. Evidence for non-obviousness should be commensurate with the scope of the claims.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EFM

/Elizabeth F. McElwain/

Primary Examiner, Art Unit 1638